

# REMARKS

Issues are addressed in the order presented in Paper 19.

## In response to ¶¶ 1 and 2 of Paper 19:

Claims 1, 2 and 4 have been amended to address the ¶ 1 § 112 rejection made in Paper 19. The claims now are definite as to the subject matter claimed. Claimed is a pharmaceutical composition comprising a KPV peptide in combination with a glucocorticoid anti-inflammatory. This mirrors the language suggested in Paper 19. Claim 2 has been amended to remove non-elected peptide species. Claim 3 has been canceled, and claim 4 now depends from claim 1.

Claim 7 has been left as previously presented but incorporates the amendment of claim 1 as to definiteness. Claims 8 and 9 have been amended consistent with the Examiner's kind recommendation. To wit, claims 8 and 9 have been combined into claim 8, and claim 9 is canceled.

## In response to ¶ 3 of Paper 19:

Claim 1 has been amended to comply with the ¶ 1, § 112 rejection of Paper 19. The language of the claims is now directed to "psoriatic disorders and contact dermatitis" as opposed to the more generic "dermatological disorders." Claim 20 has been canceled.

In response to ¶ 4 of Paper 19:

Claims 20-28 have been canceled.

In response to ¶¶ 5 and 6 of Paper 19:

A rejection of claims 1 and 2 under 35 U.S.C. § 102(b) as being anticipated by Cutuli et al. (Cutuli) is improper. The clear mandate in the application of 35 U.S.C. § 102 (b) is that to anticipate a claim, the reference must teach every element of the claim. The Federal Circuit has held: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Paper 19 notes that Cutuli teaches KPV has antimicrobial influences against microbes located in the skin. However, Cutuli nowhere teaches a combination of KPV with an anti-inflammatory agent. The combination of KPV and an anti-inflammatory agent is recited in claims 1 and 2 both prior to and after amendment. Further, claim 1 is currently directed to a combination of KPV and a glucocorticoid anti-inflammatory wherein the combination of a KPV polypeptide and glucocorticoid anti-inflammatory agent is effective for treatment of psoriatic disorders and contact dermatitis. Cutuli discusses neither the recited combination, psoriasis or contact dermatitis. Thus, these elements of claims 1 and 2 is expressly lacking from Cutuli.

Nor is the combination of an anti-inflammatory agent or, as amended, a glucocorticoid anti-inflammatory agent, with KPV, inherent in Cutuli. Cutuli teaches that

anti-inflammatory agents have a detrimental effect on the killing of pathogens. (Cutuli, p. 239.) Cutuli thus suggests the use of  $\alpha$ -MSH peptides in place of anti-inflammatory agents as opposed to or in combination with them.

Further, no mention is made of psoriasis or contact dermatitis in Cutuli, to which currently amended claims 1 and 2 are now directed. Cutuli lacks multiple elements recited in claims 1 and 2, and it is respectfully requested that Cutuli be removed as a 35 U.S.C. § 102(b) reference.

In response to ¶¶ 7 and 8 of Paper 19:

A double patenting rejection over copending Application No. 10/023,287 ("the '287 application") in view of Cutuli is improper. According to the MPEP at § 804 II B. 1, the first question to be asked in a non-statutory double patenting rejection is whether any claim in the application defines an invention that is merely an obvious variation of an invention claimed in a patent; here, a copending application, the '287 application. The features of the instant application which distinguish it from the '287 application are not merely an obvious variation, and these features make the instant application's invention patentably distinct.

First, the claims have been amended as noted above. Second, as noted in Paper 19, Cutuli deals specifically with infections secondary to *Staphylococcus aureus* and *Candida albicans*. It is not applicable to the claims as amended and neither contains nor suggests any of the features which distinguish the instant application from the '287 Application. Third, Cutuli lacks any suggestion for treatment of psoriatic

disorders or contact dermatitis with a combination of a glucocorticoid anti-inflammatory and a KPV peptide. Cutuli teaches the antimicrobial effects of KPV peptides against *Staphylococcus aureus* and *Candida albicans*, but this is not relevant to the claims as amended. Thus, it is not appropriate to combine the Cutuli reference with the '287 application for an obviousness determination.

Further, all of the claims of the '287 application are specifically directed to anti-pruritic shampoos for veterinary use. No suggestion is made of use in humans, for use in psoriasis or contact dermatitis, nor in any composition not including a shampoo. It would not have been obvious to one of ordinary skill in the art at the time the invention was made to modify the '287 application to include use in humans, eliminating a shampoo and treating psoriatic disorders and contact dermatitis. It is requested that the provisional obviousness-type double patenting rejection over the '287 application and Cutuli be removed.

In response to ¶¶ 9-11 of Paper 19:

Paper 19 states that the Cutuli reference discusses the importance of combining the antimicrobial effects of KPV with the corticosteroids and uses Cutuli for a 35 U.S.C. § 103(a) rejection. Applicant respectfully suggests this is an improper reading of the Cutuli reference. Specifically, Cutuli states: "Because reduced killing of pathogens is a detrimental consequence of therapies with corticosteroids and nonsteroidal anti-inflammatory drugs, it is important to learn whether  $\alpha$ -MSH peptides also cause this dire effect." Cutuli, pp. 233-234 (internal citations omitted). Thus, and as stated above, the

teaching of Cutuli is not to combine therapies but to determine whether  $\alpha$ -MSH peptides similarly reduced pathogen killing and whether  $\alpha$ -MSH peptides were a suitable treatment for infection. No mention of a combination is expressly made nor implied in the reference. Cutuli teaches away from a combination therapy as corticosteroids and nonsteroidal anti-inflammatories reduce the killing of pathogens. It is respectfully requested that this rejection be removed.

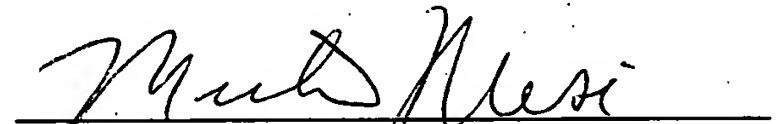
CONCLUSION

Applicant has amended claims and traversed rejections as above. Please consider the amendments and remarks and move the application on to allowance.

Respectfully submitted,

Perkins Coie LLP

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Michael J. Wise  
Registration No. 34,047

Correspondence Address:

Customer No. 34055  
Perkins Coie LLP  
Patent – LA  
P.O. Box 1208  
Seattle, WA 98111-1208  
Phone: (310) 788-9900  
Fax: (310) 788-3399